(including any ester or salt thereof) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1615 is added to read as follows:

§ 520.1615 Omeprazole.

(a) *Specifications.* Each gram of oral paste contains 0.37 gram of omeprazole.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* For treatment of gastric ulcers, 1.8 milligrams of omeprazole per pound of body weight (4 milligrams per kilogram) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 milligram of omeprazole per pound of body weight (2 milligrams per kilogram) once daily for at least an additional 4 weeks.

(2) *Indications for use.* For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 1, 1999.

George A. Mitchell,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 99–9455 Filed 4–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone Acetate and Estradiol Benzoate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health. The supplemental NADA provides for use of a trenbolone acetate-estradiol benzoate implant in steers fed in confinement for slaughter for increased rate of weight gain. At this time, FDA is also amending the regulation for trenbolone tolerances to establish an acceptable daily intake (ADI) for the drug.

EFFECTIVE DATE: April 15, 1999.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center For Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed supplemental NADA 141–043 that provides for use of Synovex® Plus™ (200 milligrams (mg) trenbolone acetate and 28 mg estradiol benzoate) implanted in the ear of steers fed in confinement for slaughter for increased rate of weight gain in addition to its approved use for improved feed efficiency. The supplemental NADA is approved as of March 16, 1999. The regulations are amended in 21 CFR 522.2478 by redesignating paragraph (c) as (d), adding paragraph (c), and revising newly redesignated paragraph (d)(1)(ii) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, an ADI for trenbolone has not been previously established. At this time, 21 CFR 556.739 is amended to provide an ADI for trenbolone.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under 21 U.S.C. 360b(c)(2)(F)(iii), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning March 16, 1999, because the supplement contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant. Market exclusivity applies only to use of the implant for increased rate of weight gain in confined steers.

FDA has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.2478 is amended by redesignating paragraph (c) as (d), reserving paragraph (c), and revising paragraph (d)(1)(ii) to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

* * * * *

(c) [Reserved]

(d) * * *

(1) * * *

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter.

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.739 is revised to read as follows:

§ 556.739 Trenbolone.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of trenbolone is 0.4 microgram per kilogram of body weight per day.

(b) *Tolerances.* A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed.

Dated: April 1, 1999.

Andrew J. Beaulieu,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–9458 Filed 4–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Narasin and Nicarbazin With Bacitracin Methylene Disalicylate and Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for using approved narasin and nicarbazin, bacitracin methylene disalicylate (BMD), and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds.

EFFECTIVE DATE: April 15, 1999.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–112 that provides for combining approved Maxiban™ (27 grams per pound (g/lb) each of narasin and nicarbazin), BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb BMD), and 3–Nitro® (45.4, 90, or 227 g/lb roxarsone) Type A medicated articles to make Type C medicated broiler chicken feeds. The Type C feed contains 27 to 45 g/ton (t) each of narasin and nicarbazin, 50 g/t BMD, and 22.7 to 45.4 g/t roxarsone. The Type C feed is used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

The NADA is approved as of March 4, 1999, and the regulations are amended by adding 21 CFR 558.76(d)(3)(xxi), 558.363(d)(2)(iii), and 558.530(d)(5)(xxv), and by amending 21 CFR 558.366(c) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of Type A medicated articles to make combination drug Type C medicated feeds. Narasin with nicarbazin and roxarsone are Category II drugs as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make a Type C medicated feed from a Category II drug. Under 21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of Type A medicated articles to make Type C medicated feeds as provided in NADA 141–112 is limited to manufacture in a licensed feed mill.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.76 is amended by adding paragraph (d)(3)(xxi) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xxi) Narasin with nicarbazin and roxarsone as in § 558.366.

3. Section 558.363 is amended by adding paragraph (d)(2)(iii) to read as follows:

§ 558.363 Narasin.

* * * * *

(d) * * *

(2) * * *

(iii) Bacitracin methylene disalicylate, nicarbazin, and roxarsone as in § 558.366.

4. Section 558.366 is amended in the table in paragraph (c) under entry ''27 to 45'' by alphabetically adding an entry for ''Naracin 27 to 45, bacitracin methylene disalicylate 50, and roxarsone 22.7 to 45.4'' to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(c) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45				